K090887

510(k) Summary
for the ORIO Intervertebral Body Fusion Cages

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the **ORIO Intervertebral Body Fusion Cages.**

Date Prepared: March 24, 2009

OCT 30 2009

1. **Submitter:**
SpineCraft LLC
2215 Enterprise Drive
Westchester, IL 60154

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. Trade name:
- ORIO-C Intervertebral Body Fusion Cervical Cage
- ORIO-PL PLIF Intervertebral Body Fusion Lumbar Cage
- ORIO-TL TLIF Intervertebral Body Fusion Lumbar Cage
- ORIO-AL ALIF Anterior/Anterolateral Intervertebral Body Fusion Lumbar Cage

Common Name: intervertebral body fusion device
Classification Name: intervertebral body fusion device - cervical
Intervertebral body fusion device - lumbar
21 CFR section 888.3080
ODP/MAX
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
ORIO Intervertebral Body Fusion Cages are substantially equivalent to similar previously cleared cervical and lumbar intervertebral body fusion devices.

4. **Description of the device:**
The ORIO Intervertebral Body Fusion Cages were developed as implants for the stabilization of the lumbar spinal column and anterior cervical spondylodesis. The ORIO implants have ridges on both their inferior and superior surfaces to prevent migration, and graft windows which help facilitate bony integration. X-ray markers are integrated for visualization of the implants after surgery.

Materials:
PEEK-OPTIMA LT1 polymer (ASTM F2026 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications)

5. **Intended Use:**
ORIO Cervical Intervertebral Body Fusion Cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. ORIO Cervical Intervertebral Body Fusion Cages used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. ORIO Cervical Intervertebral Body Fusion Cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The ORIO Lumbar Intervertebral Body Fusion Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved

level(s). ORIO lumbar intervertebral body fusion cage implants are to be used with autogenous bone graft and implanted via a transforaminal, open posterior, anterior/anterolateral or lateral approach. The ORIO Lumbar Intervertebral Body Fusion Cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**

   The ORIO Intervertebral Body Fusion Cages have the same indications and material, and similar designs as previously cleared devices.

7. **Summary of Non-clinical Tests**

   Tests performed according to ASTM F2077/F2267 indicate that the ORIO Intervertebral Body Fusion Cages meet required mechanical strengths. Some of the predicate devices have a different geometry than the ORIO Intervertebral Body Fusion Cages and do not have some test results reported in their PMA and 510 (k) summaries, therefore, additional acceptance values for testing have been utilized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2009

SpineCraft, LLC
% Mr. J.D Webb
The OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K090887
Trade/Device Name: ORIO-C Intervertebral Body Fusion Cervical Cage
ORIO-PL PLIF Intervertebral Body Fusion Lumbar Cage
ORIO-TL TLIF Intervertebral Body Fusion Lumbar Cage
ORIO-AL ALIF Anterior/Anterolateral Intervertebral Body Fusion Lumbar Cage

Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, ODP
Dated: October 30, 2009
Received: October 30, 2009

Dear Mr. Webb:

This letter corrects our substantially equivalent letter of October 30, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090887

Device Name: ORIO lumbar intervertebral body fusion cages

Indications for Use:

The ORIO lumbar intervertebral body fusion cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). ORIO lumbar intervertebral body fusion cage implants are to be used with autogenous bone graft and implanted via a transforaminal, open posterior, anterior/anterolateral or lateral approach. The ORIO lumbar intervertebral body fusion cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090887

Indications for Use

510(k) Number (if known): K090887

Device Name: ORIO cervical intervertebral body fusion cages

Indications for Use:

ORIO cervical intervertebral body fusion cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. ORIO cervical intervertebral body fusion cages used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. ORIO cervical intervertebral body fusion cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090887